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, 2003

By: Whare When Diane Dunn

Atty. Docket No.: 0154.310US

Examiner: Gerald R. Ewoldt

DECLARATION OF JUHA

PUNNONEN AND CHIA-CHUN J. CHANG UNDER 37 CFR §1.131

Art Unit: 1644

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Juha Punnonen, et al.

Application No.: 09/760,388

Filed: January 10, 2001

For: MONOCYTE-DERIVED DENDRITIC CELL SUBSETS

Commissioner for Patents
P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

We, Juha Punnonen and Chia-Chun J. Chang, state as follows:

- 1. We are the co-inventors of the above patent application ("the application").
- 2. We understand that the Examiner has cited Rissoan *et al.*, *Science* 283:1183-86 (Feb. 1999) ["Rissoan"], which published on February 19, 1999, as prior art against the claims of the application. We understand that the Examiner takes the view that Rissoan discloses antigenpresenting cells that substantially lack IL-12 production and induce Th2 differentiation. We understand the Examiner also takes the position that additional characteristics of the claimed cells (e.g., devoid of CD1a surface marker) are inherent to the cells disclosed in Rissoan.
- 3. We understand that the Examiner has also cited Ito et al., J. Imunol. 163:1409-19 (1999) [hereinafter "Ito"], which published in August 1999, as prior art against the claims of the application. We understand that the Examiner takes the view that Ito discloses antigen-presenting cells that are devoid of CD1a surface marker and that additional characteristics of the claimed cells (e.g., cells that substantially lack IL-12 production) are inherent to the cells disclosed in Ito.
- 4. To the extent that either Rissoan or Ito is asserted to disclose subject matter relevant to the claimed invention, we had reduced the claimed invention to practice in the United

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States of America before February 19, 1999 and thus before the publication of either Rissoan or Ito.

- 5. It is the practice in our laboratory for us and technicians working under our direction and control to keep laboratory notebooks detailing experiments and recording accurately and contemporaneously the experiments and results.
- 6. We have attached as Exhibit A true copies of pages 80, 92, and 93 from Laboratory Notebook No. 114 by Chia-Chun J. Chang. These pages describe experimental work that is substantially the same as the work described in the application, including, e.g., page 55 and Fig. 2 of the application. Briefly, the experimental results set forth in Lab. Notebook No. 114, page 80 showed, among other things, that our dendritic cells expressed substantially less CD1a surface marker than conventional dendritic cells. The results shown in Lab. Notebook No. 114, pages 92-93 showed, among other things, that dendritic cells expressing substantially less CD1a surface marker than conventional dendritic cells also substantially lacked CD14 expression, but expressed CD33 surface marker. We concluded our dendritic cells expressed substantially less CD1a surface marker than conventional dendritic cells, substantially lacked CD14 expression, but expressed CD33.

Exhibit A also includes true copies of pages 3-4 from Lab. Notebook No. 212 by Chia-Chun J. Chang. These pages describe experimental work that is substantially the same as the work described in the application, including, e.g., page 55 and Fig. 2 of the application. Briefly, the experimental results in Lab. Notebook No. 212, pages 3-4 demonstrated, among other things, that dendritic cells which expressed substantially less CD1a surface marker than conventional dendritic cells did express CD13 and CD11c surface markers. We concluded our dendritic cells expressing substantially less CD1a than conventional dendritic cells expressed CD33 and CD11c.

Exhibit A also includes a true copy of page 20 from Lab. Notebook No. 212 by Chia-Chun J. Chang. This page 20 describes experimental work that is substantially the same as the work described in the application, including, e.g., pages 56-58 and Fig. 4 of the application. The results in Lab. Notebook No. 212, page 20 demonstrated, among other things, that the dendritic cells which expressed substantially less CD1a surface marker than conventional dendritic cells did express CD83 surface marker. We concluded our dendritic cells expressing substantially less CD1a surface marker than conventional dendritic cells expressed CD83.

7. We have masked the dates on each of the pages of Exhibit A. However, the work described therein was performed in the United States of America by at least one of us, or a technician under our direction and control, prior to February 19, 1999 and thus before the publication of either Rissoan or Ito.

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We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 10/01/03

Dated: 9/19/03

Juha Punnonen

Chia-Chun J. Chang

Attachment:

Exhibit A